

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
 v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9009

Bartle, J.

February 26, 2013

Clyde L. Minor, Jr. ("Mr. Minor" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Shelle Minor, Mr. Minor's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2011, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated June 16, 2002, Dr. Dlabal attested in Part II of Mr. Minor's Green Form that claimant suffered from mild aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin®

3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

and/or Redux™.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$784,920.⁵

Dr. Dlabal also attested in claimant's Green Form that Mr. Minor did not suffer from aortic stenosis. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)e). As the Trust does not contest Mr. Minor's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In April, 2011, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Dlabal's finding that claimant did not have aortic stenosis with an aortic valve area less than

4. Dr. Dlabal also attested that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

one square centimeter by the Continuity Equation. In support of this conclusion, Dr. Penkala stated:

On the study dated 6/16/02 the claimant has evidence of aortic valve sclerosis/mild [aortic insufficiency] to at most mild [aortic stenosis]/mild [aortic insufficiency] by velocity criteria.

The [echocardiogram] study dated 4/13/10 is confusing. The peak aortic valve velocity is 4.85 m/s consistent with severe aortic stenosis (peak velocity >4 m/s). The peak gradient was 4.85 m/s for peak gradient 94 mm Hg also consistent with severe aortic stenosis. The [aortic valve area] was not calculated on the report/study. When I calculated it by the continuity equation on my own I got 1.19 cm^2 - more consistent with moderate-severe aortic stenosis.

The claimant had a heart [catheterization] done 5/11/10. This showed mean AoV gradient 41mm Hg also consistent with severe [aortic stenosis] but [aortic valve area] 1.1 cm^2 by simultaneous recordings placing it in the moderate-severe range. Finally, the claimant underwent [aortic valve replacement] on 8/3/10. The surgeon found a calcified functionally bicuspid (although trileaflet) valve and confirmed post-op diagnosis of severe aortic stenosis.

Although some of the criteria fall just outside the designated range for severe aortic stenosis, I think that in totality the claimant had severe aortic stenosis along with mild [aortic insufficiency] at the time of surgery.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that Mr. Minor was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that he was entitled to Matrix A-1 level benefits because "Dr. Penkala chose to use a different criterion for determining the presence of aortic stenosis" than the method provided by the Settlement Agreement -- calculation of the aortic valve area by the Continuity Equation.⁷ Claimant also submitted declarations from his attesting physician, Dr. Dlabal, and from Manoj R. Muttreja, M.D. Dr. Dlabal's declaration concluded, in relevant part, that "a qualified Board-Certified Cardiologist would conclude that the patient did not have aortic stenosis with an aortic valve area less than 1.0 cm.² as determined by the Continuity Equation." Dr. Muttreja's declaration concluded, in relevant part, that:

In order to determine the patient's [aortic valve area], the cardiologist must calculate it by using the Continuity Equation or the Gorlin formula. On the basis of these calculations, Mr. Minor had an [aortic valve area] that was not less than 1.0 cm.².

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Minor's claim.

7. Claimant also argued that a reduction factor such as aortic stenosis should not reduce a claim to the B-1 Matrix unless the reduction factor was present at the same time a claimant was first diagnosed as FDA positive. Given our resolution of this claim, we need not address this issue.

Thus, according to claimant, he should receive Matrix A-1 benefits because the auditing cardiologist did not find that claimant had aortic stenosis with an aortic valve area less than one square centimeter by the Continuity Equation, as required by the Settlement Agreement.

The Trust then issued a final post-audit determination, again determining that Mr. Minor was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Minor's claim should be paid. On November 29, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8711 (Nov. 29, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 21, 2012, and claimant submitted a sur-reply on November 7, 2012. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

In support of his claim, claimant reasserts the arguments that he made during contest. In response, the Trust argues that Mr. Minor's claim properly was reduced to the B-1

Matrix because, based upon the "totality" of claimant's medical evidence, claimant had aortic stenosis prior to his aortic valve replacement surgery.

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for his attesting physician's representation that Mr. Minor does not have aortic stenosis. As noted, the Settlement Agreement defines aortic stenosis as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation." Settlement Agreement § IV.B.2.d. (2)(c)i)e).

In connection with the audit of Mr. Minor's claim, the Trust's auditing cardiologist reviewed claimant's echocardiograms dated June 16, 2002 and April 13, 2010. In both instances, the auditing cardiologist concluded that claimant did not have aortic stenosis with an aortic valve area less than one square centimeter by the Continuity Equation.

As to claimant's June 16, 2002 echocardiogram, the Trust stated in its Final Post-Audit Determination:

There is no dispute that Dr. Penkala did not find aortic stenosis with an aortic valve area < 1.0 square centimeter on your June 16, 2002 echocardiogram study. Dr. Penkala observed, "On the study dated 6/16/02 the claimant has evidence of aortic valve sclerosis/mild [aortic insufficiency] to at most mild [aortic stenosis]/mild [aortic insufficiency] by velocity criteria."

As to claimant's April 13, 2010 echocardiogram, in her report, Dr. Penkala also admitted that her calculation of claimant's aortic valve area by the Continuity Equation was 1.19 cm².

We reject the Trust's assertion that it may find the presence of aortic stenosis from the "totality" of claimant's medical evidence rather than based on a measurement of claimant's aortic valve area by the Continuity Equation. In PTO No. 8562 (Nov. 15, 2010), we rejected a similar argument raised by a claimant who sought to negate a finding of aortic stenosis by relying on evidence other than a measurement of his aortic valve area by the Continuity Equation. As we stated, "We reject claimant's argument that he may disprove the existence of aortic stenosis by a method other than the Continuity Equation, which is specifically required by the Settlement Agreement." Id. at 12 n.11 (citing Settlement Agreement § IV.B.2.d.(2)(c)i)e)). If a claimant cannot rely on any evidence other than the measurement specified in the Settlement Agreement in determining when the reduction factor of aortic stenosis is present, the same is true for the Trust.

The court must apply the Settlement Agreement as written. As the Trust concedes that claimant does not have aortic stenosis as defined by the Settlement Agreement, the Settlement Agreement mandates that the present claim cannot be reduced to the B-1 Matrix.

For the foregoing reasons, we conclude that claimant has met his burden of proving that he is entitled to Matrix A-1 benefits. Therefore, we will reverse the Trust's denial of Mr. Minor's claim for Matrix A-1, Level III benefits and the related derivative claim submitted by his spouse.